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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,485	01/29/2004	Steve T. Cho	6813USD1	5052
23492	7590	04/04/2005	EXAMINER	
ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008			NGUYEN, CAMTU TRAN	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/767,485

Applicant(s)

CHO, STEVE T.

Examiner

Camtu T. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-37 and 42-44 is/are rejected.
- 7) ☒ Claim(s) 38-41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's preliminary amendment filed on April 5, 2004. Claims 1-32 have been cancelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33, 39, and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (U.S. Patent No. 5,860,957) in view of Palasis (U.S. Patent No. 6,689,103). Jacobsen et al discloses in Figures 1 and 2 an electronically controlled drug delivery system comprising elements set forth in these claims including a microprocessor (40), a display screen (50), a keypad (42) and a memory (52) all of which are coupled to the microprocessor (40), an activation button (44), and a drug storage and delivery module (20). The Jacobsen et al system would inherently have a reservoir in the drug storage module. The Jacobsen et al system does not teach a cartridge comprising an array of microneedles. Palasis discloses in Figures 1 and 2 a fluid delivery system (20) comprising an injection catheter (40) having a tubular member (44) defining a lumen (46), a distal end (48), and a plurality of microneedles (60) disposed proximate the distal end (48) of the injection catheter (40). Therefore it would have been obvious to one

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skilled in the art to utilize the injection catheter taught by Palasis in Jacobsen et al's drug delivery module (20) as such would decrease the level of pain when a patient receiving an injection.

Claims 33, 39, and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mann et al (U.S. Patent No. 6,551,276) in view of Palasis (U.S. Patent No. 6,689,103). Mann et al discloses in Figures 1-4 an external infusion device with programming capabilities comprising elements as recited in these claims including a processor (18), a LCD (28), a keypad (20), and a memory (22), all of which are coupled to the processor (18), a drive mechanism (32) coupled to the processor (18) and to a reservoir (34) which is connected to an outlet (36) where tubing and set (38) expels fluid in the reservoir (34) into a body of a user. The Mann et al device does not teach a cartridge comprising an array of microneedles. Palasis discloses in Figures 1 and 2 a fluid delivery system (20) comprising an injection catheter (40) having a tubular member (44) defining a lumen (46), a distal end (48), and a plurality of microneedles (60) disposed proximate the distal end (48) of the injection catheter (40). Therefore it would have been obvious to one skilled in the art to utilize the injection catheter taught by Palasis in Mann et al's tubing and set (38) as such would decrease the level of pain when a patient receiving an injection.

Claims 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobson et al (U.S. Patent No. 5,860,957) or Mann et al (U.S. Patent No. 6,551,276), as modified above, in view of Garstein et al (U.S. Patent No. 6,379,324) and further in view of Saadat (U.S. Patent No. 5,899,915). Jacobsen et al discloses in Figures 1 and 2 an electronically controlled drug delivery system comprising elements set forth in these claims but does not teach each individual microneedle of the array comprising elements as recited. Garstein discloses on figure 22 an

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array of plurality of silicon microneedles 465 on a substrate 410 comprising elements as recited in these claims including a fluidic communication channel 460 between microneedle tip and the microneedle broad base. Figure 22 illustrates an array of cylindrically shaped microneedles and Garstein further points out that other shapes could be used than a cylindrical shape such as conical-shaped body 530 as illustrates on figures 23 and 25 (column 16 lines 51-67, column 17 lines 1-33, column 18 lines) but Garstein et al lack the teaching of the microneedle having a beveled and non-coring tip that has the ability to pierce. Saadat discloses in Figure 11A tube 101 having beveled sharpened tip (102) and lumen (103) and that the bevel of tip (102) renders the tip non-coring so that when the beveled end of tube 101 is inserted into the tissue. Therefore, it would have been obvious to one of ordinary skill in the during the time of the invention to modify Jaconsen et al's Jacobsen et al's drug delivery module (20) or Mann's Mann et al's tubing and set (38) to include Garstein's array of microneedles having tips suggested by Saadat as such beveled end would define a sharp leading point on the tip that is able to pierce the tissue smoothly and also would prevent a core tissue from forming in and block the lumen or fluid channel of the microneedle when inserted into the tissue because a flap of tissue is cut and folded back, rather than severed.

Allowable Subject Matter

Claims 38-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 703-305-0537. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Camtu Nguyen
March 17, 2005


Henry Bennett
Supervisor/Patent Examiner
Group 3700